Electronic Submissions

eCTD and Beyond

RAPS 2004
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Where are we today…

- Accepting BLA, IND, NDA, ANDA, DMF and related submissions in electronic format
- Part 11 electronic signatures
- Secure email
- Electronic internal routing

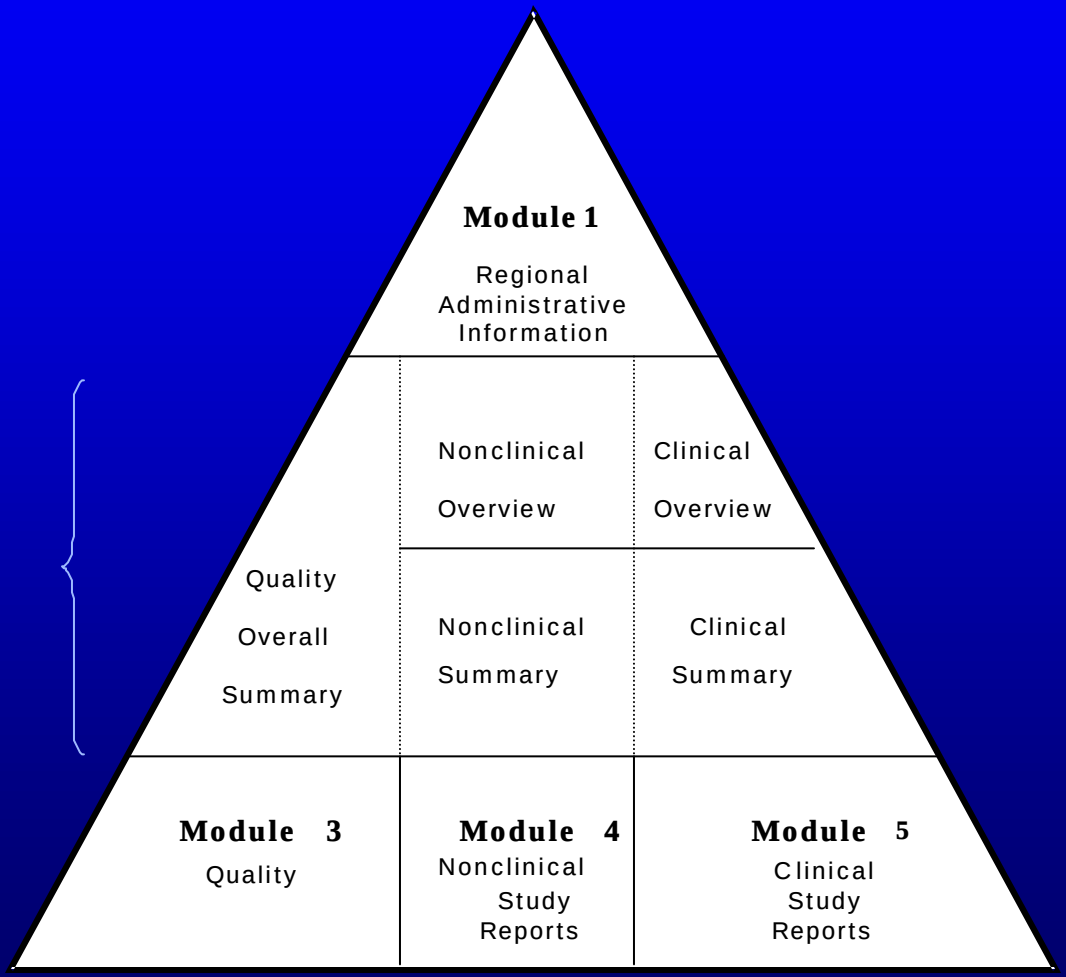
Electronic Document Room (EDR)

- **Provides the core system for CBER electronic submissions**
  - **Archive for all electronic submissions**
  - **Provides the user interface through which reviewers access, download, and review submissions**
  - **Interfaces to corporate databases for submission meta-data (i.e., BIMS, RMS/BLA)**
- **Incorporates**
  - **Electronic Secure Messaging (ESM)**
  - **E-Routing**

Where are we going…

- Moving towards a paperless submission environment
- Working on becoming a standards based organization
  - eCTD is just such a standard
  - Structured Product Labeling
  - HL7 standards
- Gateway

Diagrammatic Representation of the ICH Common Technical Document per Step 4 Guideline



Not part of CTD

Module 2

CTD

ICH eCTD Issues

- **eCTD Specification Stability Needed**
  - **eCTD Solution Providers Can Not Develop Toward "Moving Target"**
- **Major Releases of eCTD Specification**
  - **Announced at least 2 years prior to step 4**
  - **Incorporate major architectural needs**
- **Minor Releases Between to fix deficiencies**
- **2 Year Plan for Next eCTD Major Release (2006)**

Electronic Submissions Using eCTD Specifications

- **Guidance Published August, 2003**
- **eCTD Specifications**
  - **FDA eCTD Table of Contents Headings and Hierarchy**
  - **FDA Module 1 Specification**
  - **FDA Modules 2 to 5 Specification**
  - **Study Tagging File Specification**
- **Specifications Available On-Line**

http://www.fda.gov/cder/regulatory/ersr/ectd.htm

eCTD Considerations

- XML-based eCTD Backbone replaces PDF Table of Contents
  - Backbone defines what can be submitted, not what must be submitted
- Document granularity in accordance with ICH eCTD agreements
- Once a submission is sent in eCTD format all future submissions for that application should be in eCTD format

What doesn't change

- Data files submitted in SAS XPORT format
- Documents submitted in PDF Format
- PDF should be text-based
  - Understandable that aged legacy reports are scanned
  - Current documents, including reports from CROs, should be in text-based electronic format, e.g., MS Word or text-based PDF
- Draft labeling submitted in MS Word

Submission Processing Tool

- **EVS Processing Tool**
  - Validates presence of required files
  - Validates eCTD Backbone against DTD
  - Validates location of content referenced in eCTD Backbone.
  - Builds and maintains the comprehensive TOC
  - Makes submission available for viewer & reviewer
- **Adherence to the eCTD specification is critical**
  - Do not add or modify leafs within the backbone

Submission Review Tools

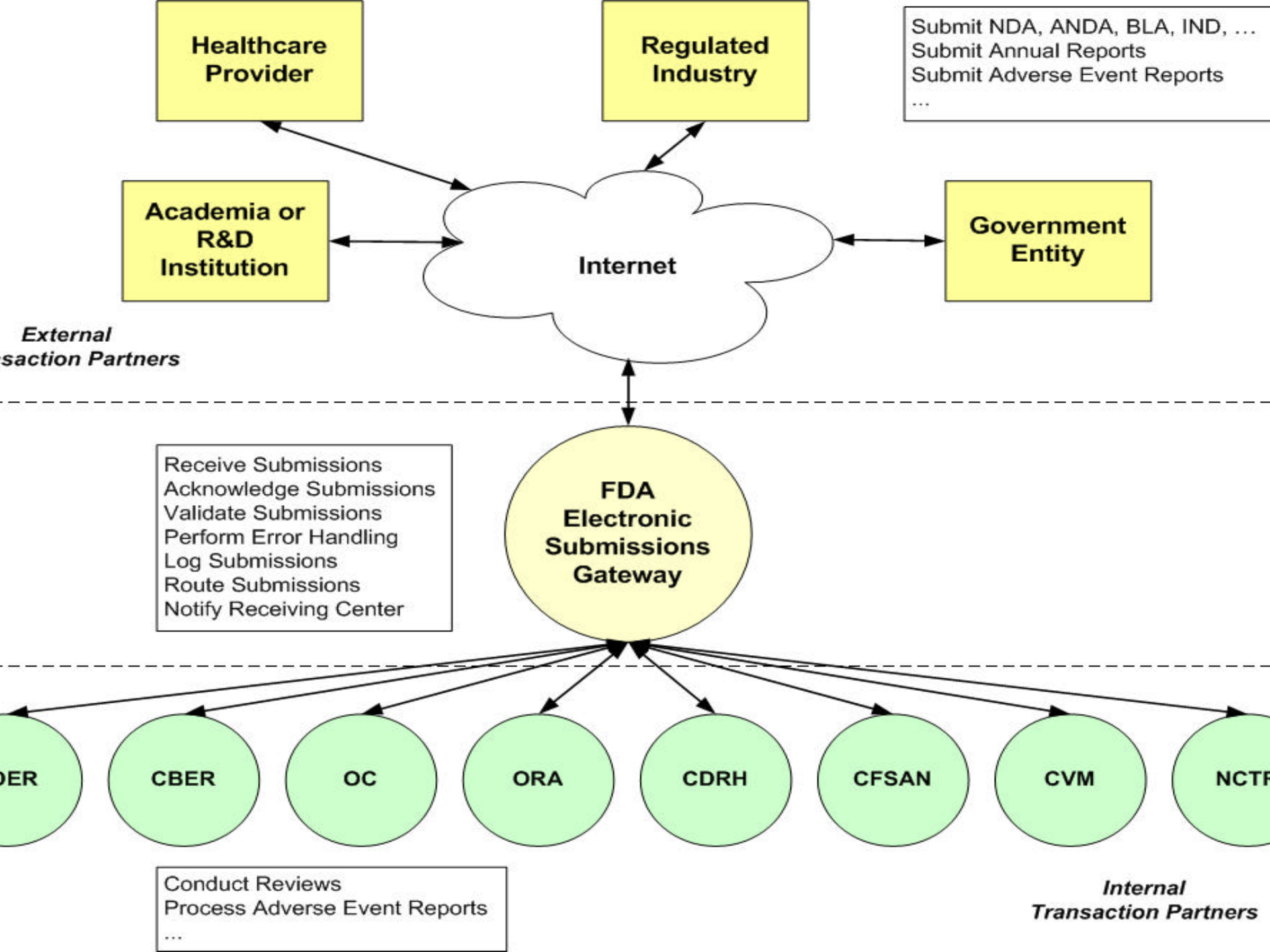
- **EVS Viewer – first release**
  - **Provides reviewers with direct access to submissions**
  - **Provides both submission-based and "Cumulative Table of Contents" view of applications**
  - **Provides a module based view of submissions**
  - **Provides download capability for off-line reviewing**
- **Not currently integrated into CBER edr**
- **Being evaluated for replacement**

FDA Gateway Program

- **Project Leads**
  - **Project Officer – Mark Gray OC/OCIO**
  - **Program Manager – Michael B. Fauntleroy CBER/OD**
  - **Technical Lead – Joseph Montgomery CBER/OIM**

FDA GATEWAY

- **New Gateway project**
- **Web enabled**
- **Ultimately will replace present ESTRI Gateway**
- **Participants**
  - CBER
  - CDER
  - CDRH
  - CFSAN
  - OC/OCIO
  - ORA


Healthcare Provider
Regulated Industry
Submit NDA, ANDA, BLA, IND, …
Submit Annual Reports
Submit Adverse Event Reports
…
Academia or R&D Institution
Internet
Government Entity
External saction Partners
Receive Submissions
Acknowledge Submissions
Validate Submissions
Perform Error Handling
Log Submissions
Route Submissions
Notify Receiving Center
FDA Electronic Submissions Gateway
DER
CBER
OC
ORA
CDRH
CFSAN
CVM
NCTR
Conduct Reviews
Process Adverse Event Reports
…
Internal Transaction Partners

FDA Gateway

- **Receiving Pre-Marketing and Marketing Submissions and Amendments**
  - INDs, IDEs, etc.
  - BLAs, NDAs, ANDAs, PMAs, 510(k)s, etc.
- **Adverse Event Reporting**
  - AERS
  - VAERS
  - BAERS
  - etc.
- **External Communications**

References

- CBER Contact for information on electronic submissions

  http://www.fda.gov/cber/esub/esub.htm

  and

  esubprep@fda.cber.gov

- eCTD Specifications

  http://www.fda.gov/cder/regulatory/ersr/ectd.htm

- International Conference on Harmonization

  http://www.ich.org

We're Here to Help You!

WWW.FDA.GOV/CBER

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